

*REMARKS/ARGUMENTS**The Pending Claims*

Claims 1 and 3-25 are pending. Claim 2 was previously cancelled. Claims 14-25 are withdrawn from consideration as drawn to non-elected inventions in response to the earlier restriction requirement. No claim amendments are made herein.

*35 U.S.C. § 112, First Paragraph**A. Written Description*

Claims 1 and 3-13 stand rejected as lacking adequate written description. The Office Action alleges that in the absence of “binding specificity associated with the complete structure of any and all antibody [sic],” the specification fails to demonstrate that Applicants were in possession of the claimed genus of antibodies (Office Action at p. 5). The Office Action admits that the specification discloses a number of monoclonal antibodies, and correctly states that a genus is adequately described if the disclosure presents “a sufficient number of representative species that encompass the genus.” M.P.E.P. § 2163.

Applicants respectfully submit that the disclosed monoclonal antibodies, combined with the disclosure of the specification as a whole, are sufficient to convey possession of the invention. However, Applicants also submit that specific characterization of particular antibodies is not required to provide written description of the present claims. The Office Action states: “Without guidance as to the binding specificity of the antibody in the claimed compound, it is unpredictable which undisclosed antibody when linked to toxin via an intact glycosyl linking group is effective for treating cancer in humans by delivering the toxin to the right tissue or cell type” (Office Action at p. 6). However, none of the present claims makes any reference to a requirement that the antibody-toxin conjugate “is effective for treating cancer in humans by delivering the toxin to the right tissue or cell type.” Terms which appear in the specification but are not recited in the claim should not be read into the claim. *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369, 67 U.S.P.Q.2d 1947, 1950 (Fed. Cir. 2003) (claims must be interpreted “in view of the specification” without importing limitations from the specification into the claims unnecessarily); see also M.P.E.P. § 2106(II)(C).

The Office Action further provides extensive discussion of the importance of an antibody's amino acid sequence to its ability to bind an antigen. However, in the absence of any claim term relating to specificity for a particular antigen, Applicants submit that the full possession of the scope of the term "antibody" is conveyed on the basis that general preparation and use of antibodies is routine in the art. See, e.g., U.S. Patent and Trademark Office Written Description Guidelines (2000), Example 13.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the written description rejection.

*B. Enablement*

Claims 1 and 3-13 stand rejected as lacking enablement. The Office Action alleges that the present specification "does not reasonably provide enablement for how to use such compound as set forth in claims 1 and 3-13 without guidance as to the binding specificity of [the] antibody in the claimed compound" (Office Action at p. 14).

Although the Office Action admits that the specification provides enabling disclosure for several monoclonal antibodies, the Office Action alleges that "without guidance as to the binding specificity of the antibody in the claimed compound, it is unpredictable which undisclosed antibody when linked to toxin via an intact glycosyl linking group is effective for treating cancer in humans by delivering the toxin to the right tissue or cell type" (Office Action at p. 15). The Office Action further alleges that "it is unpredictable whether any and all compound [sic] comprising any antibody linked to any toxin via an intact glycosyl linking group and spacer moiety or amplifier moiety can be used as a pharmaceutical composition for treating any diseases *in vivo*" (Office Action at p. 16).

As discussed above with respect to the written description rejection, it is not proper to read additional limitations from the specification into a claim. The present claims do not recite the use of the compounds in treating cancer in humans, or in treating diseases *in vivo*. Therefore, it is improper to reject the claims for lack of enablement of such uses. In this respect, M.P.E.P. § 2164.01(c) states:

[W]hen a compound or composition claim is not limited by a recited use, any enabled use that would reasonably correlate with the entire scope of that claim is sufficient to preclude a rejection for nonenablement based on

how to use. If multiple uses for claimed compounds or compositions are disclosed in the application, then an enablement rejection must include an explanation, sufficiently supported by the evidence, why the specification fails to enable *each disclosed use*. In other words, if *any use* is enabled when multiple uses are disclosed, the application is enabling for the claimed invention. (emphasis added)

One of ordinary skill in the art would have been well aware of the range of therapeutic antibodies available and their respective *in vivo* and *in vitro* uses at the time the present application was filed. Moreover, the present specification states that modification of such polypeptides according to the methods of the present invention, “enhance” their “use as a therapeutic or diagnostic agent” (page 6, lines 19-20). Therefore, in considering the teachings of the specification, one of ordinary skill in the art would understand that the presently claimed compounds could be used in existing therapeutic and diagnostic uses for the antibody employed in the compound.

Based on the foregoing, Applicants respectfully submit that the Office Action fails to make out a prima facie case of non-enablement. In any event, however, Applicants submit herewith a Declaration Under 37 C.F.R. § 1.132 by co-inventor Shawn DeFrees, which further addresses the enablement issue.

By way of the Rule 132 Declaration, Dr. DeFrees explains that the claims of the present application are directed to compounds comprising an antibody joined to a toxin by way of an intact glycosyl linking group and a bond or spacer moiety and that, in order to prepare and use such compounds based on the information in the patent application, it is not necessary to know the binding specificity of the antibody for any target. Dr. DeFrees notes that, well prior to 2006 (i.e., the filing date of the present application), a variety of antibodies were being used for therapeutic purposes and that the compounds claimed in the present application, incorporating those antibodies, can be used in the same manner as such antibodies.

Accordingly, Dr. DeFrees confirms that the disclosure in the present application, in combination with the state of the art at the time the present application was filed in 2006, would have allowed one of ordinary skill in the art to make and use the claimed invention without undue experimentation.

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the enablement rejection.

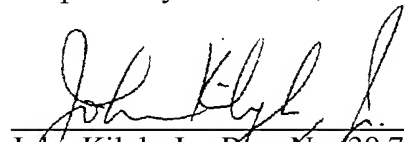
*35 U.S.C. § 102(e)*

Claims 1 and 3-11 stand rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent 7,125,843 ("the '843 patent"). As noted by the Office Action, the '843 patent has an inventor, Shawn DeFrees, in common with the present application. Applicants submit herewith a Declaration Under 37 C.F.R. § 1.132 by co-inventor Shawn DeFrees, stating that the cited portions of the presently claimed invention disclosed but not claimed in the '843 patent were invented by him or derived from him (i.e., Shawn DeFrees). Therefore, the '843 patent is not "by another" as required under 35 U.S.C. § 102(e), and the '843 patent is effectively removed as prior art against the present claims. Under the circumstances, Applicants respectfully request reinstatement and withdrawal of the anticipation rejection.

*Conclusion*

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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Date: February 26, 2010